Remarks

Claims 1-19 are currently pending and stand rejected. Applicant has amended claims 1-18, cancelled claim 19, and added new claims 20-24. Applicant encloses credit card payment form PTO - 2038 in the amount of $75.00 to cover 3 additional claims.

Rejections under 35 U.S.C. §112, ¶2

In the Office Action dated December 29, 2004, the Examiner rejected claim 9 under 35 U.S.C. §112, ¶2, as being indefinite stating that the preamble is not commensurate with that of claim 9 from which it depends. Applicant believes the Examiner meant to apply this rejection to claim 10, and has amended claim 10 so that its preamble properly includes the language of claim 9 from which depends.

Rejection under 35 U.S.C. §102(b) and §103

The Examiner has rejected claims 11, 16, and 19 under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 4,795,463 to Gerow et al. Applicant respectfully disagrees for the following reasons.

The Examiner states that Gerow teaches a method of detecting a rupture, including "implanting a prosthesis containing a fill (chemical indicator)," (Gerow's radioopaque marker), and "detecting a change locally around the prothesis using x-ray for indication of leaking out of said indicator from the prosthesis." *See* Office Action, p. 2. Firstly, Gerow discloses use of a radiopaque marker (detectable by x-ray) placed on the exterior surface of a prosthesis (or integrated into the envelope material of the implant at time of manufacture) and using an x-ray to view the perimeter to see a change in the shape of the prosthesis that would show a rupture or fold, after it has occurred. Gerow's radioopaque marker is used to label or mark the external perimeter of the implant and does not teach a biologically compatible rupture indicator disposed within the implant itself with the capability of leaking out and causing a body change

detectable to the patient to indicate rupture, elements required by all of the present claims, including claims 11 and 16 addressed in the Examiner's rejection.

Specifically, the present claims, as amended herein, are directed to a method of detecting rupture of a prosthesis including the elements of implanting a prosthesis having at least one elastomeric envelope with a filling material contained therein; adding into the prosthesis a biologically compatible rupture indicator, capable of leaking out and causing a body change detectable to the patient upon rupture of the envelope; and detecting the body change of the rupture indicator (claims 11 and 16).

Despite the Examiner's assertions, Gerow does not disclose a rupture indicator capable of "leaking-out" from the interior prosthesis to cause a body change detectable to the patient. Rather, Gerow merely teaches a method for marking the perimeter with a radioopaque marker affixed to the exterior surface of the implant and covered in silicone rubber (*see* Gerow col. 6, lines 57-60) to look for changes in shape of the implant (by use of xray examination) noting a rupture or fold of the envelope has occurred. Gerow's radioopaque marker is not causing a body change detectable to the patient, as in the present invention.

Gerow does not teach or suggest the inclusion of a biologically compatible rupture indicator within a prosthesis so that it may leak out and cause a body change detectable to the patient, warning or alerting the user of rupture or impending rupture of the implant filling material from the prosthesis. For at least these reasons, Gerow does not teach all elements of Applicants present claims, including a rupture indicator disposed within the prosthesis itself and capable of release from the prosthesis by leaking out, whether independently from, or in combination with the filling material, and causing a body change detectable to the patient.

The present invention provides numerous advantages over the state of the art, including Gerow, as the rupture indicator causes a body change detectable to the patient, and hence, the patient is able to self-detect rupture or impending rupture on his/her own *without* the need for a physician visit to undergo a diagnostic test, such as an xray

examination as in Gerow, which a physician or other technician must perform and evaluate. The state of the art (including Gerow) requires regular doctor visits and performance of diagnostic tests, such as MRI or x-ray exams, on a regular, scheduled basis, which are extremely costly and inconvenient to the patient, in order to detect a rupture which has already occurred and inflicted harm on the patient for an unknown period of time. In addition to the advantages of reduced costs and increased convenience to the patient, the present invention allows the further advantage of self-~~detection~~ before a rupture occurs and before any harm is experienced by the patient.

Rejection under 35 U.S.C. 103(a)

The Examiner has rejected claims 1-19 under 35 U.S.C. 103(a) as being anticipated by U.S. Patent No. 4,969,899 to Cox in view of U.S. Patent No. 4,795,463 to Gerow et al. Specifically, the Examiner cites Cox for teaching both an external and internal envelope, but notes Cox is silent regarding a chemical indicator for indicating rupture within the external envelope and cites Gerow for teaching use of "radioopaque materials on the envelope and further teaches it is possible to use a radioopaque material in the silicone gel fill material. See column 5, lines 3-10." *See* Office Action, p. 3. Applicant respectfully disagrees for the following reasons.

There is no suggestion in Gerow to mark the silicone gel itself, and in fact, a teaching away from the practice. Gerow does not disclose rupture indicator of the present invention within the envelope of the implant, despite the Examiner's suggestion otherwise, and further does not disclose or suggest the capability of leaking out and causing a body change detectable to the patient. Gerow's teaching is limited to marking the exterior surface of an implant with a radioopaque label to mark the implant's shape, so that a change of shape may be determined (only by) x-ray examinations.

Cox also fails to disclose or suggest the rupture indicator of the present invention capable of leaking out and causing a body change detectable to the patient. Rather, Cox discloses an inflatable implant with a fill valve to allow for injection and removal of

fluid through tubing into an internal lumen of the prosthesis, to allow for filling of implant after implantation in the body, requiring a smaller incision at time of surgery. *See* Cox col. 2, lines 23-24 & 42-44. Cox is concerned with injection and removal of implant filler rather than a rupture indicator, as in Applicants claim 9. Further, there is no suggestion to combine the implant of Cox, concerned with minimizing the invasiveness of surgery, with the disclosure of Gerow concerned with x-ray determination of rupture and fold of the envelope. In fact, one would likely interfere with the other, for instance placing a radioopaque marker on an existing surface of an implant, which would have to be in place prior to implantation, likely interfering with Cox's goal of minimize surgical incisions by later inflating it. Such a combination would lead to marking one or both the internal and external envelopes in Cox with the radioopaque marker of Gerow and x-raying the implant to determine a change in the shape of the perimeter of the implant, to note rupture or fold of an envelope. Such a combination does not teach or suggest all elements of the present claims where the rupture indicator is contained within the prosthesis and able to leak-out and cause a body change detectable to the patient.

Further, neither Gerow or Cox teaches, nor does their combination suggest, a body change detectable to the patient which is at least one dye, as in Applicant's claims 2 and 4, or specifically methylene blue as in claim 3.

Neither Gerow or Cox teaches, nor does their combination suggest a rupture indicator which is an odor generating agent that releases a smell as the body change detectable to the patient when leaking out from the prosthesis, as in Applicants claim 5.

Neither Gerow or Cox teaches, nor does their combination suggest, the rupture indicator as a sensation agent which causes a local sensation as the body change detectable to the patient when leaking out from the prosthesis, as in Applicant's claim 6.

Neither Gerow or Cox teaches, nor does their combination suggest a valve disposed in the elastomeric envelope for adding or removing rupture indicator to or from the

prosthesis, as in Applicant's claim 9, or further that the valve is self-sealing, as in Applicant's claim 10.

Neither Gerow or Cox teaches, nor does their combination suggest, a rupture indicator that upon leaking out causes a change detectable to the patient in a body secretion as in Applicant's claim 12 or specifically an odor emanating from or a change of color in the body secretion as in Applicant's claims 14 and 15, respectively.

Neither Gerow or Cox teaches, nor does their combination suggest, a rupture indicator that upon leaking out causes the change detectable to the patient due to presence of the indicator or a metabolized product thereof in a body secretion or peripheral blood as in Applicant's claim 13.

Neither Gerow or Cox teaches, nor does their combination suggest, a rupture indicator that upon leaking out causes a locally to a portion of the body around the prosthesis detectable to the patient as in Applicant's claim 16, and specifically a local skin color change (claim 17), or a local sensation (claim 18).

Applicant's new claims 20-23 all include the elements two elastomeric envelopes, a first elastomeric envelope containing the filling material and a second elastomeric envelope containing a rupture indicator, the second envelope external to the first envelope. (Support for these new claims can be found in the specification and Figures 1-2. No new matter is added by introduction of these claims.) The rupture indicator is capable of leaking out and causing a body change detectable to the patient upon rupture of the second external envelope, prior to rupture of the first internal envelope, hence alerting the user of impending rupture of the first internal envelope and the filling material contained therein.

Neither Gerow or Cox teaches, nor does their combination suggest, a rupture indicator that causes a body change detectable to the patient, that serves to warn or alert the patient of impending rupture of the internal envelope containing the filling material of the implant. Specifically, Gerow requires the leakage or escape of silicone gel from the

implant into the surrounding breast tissues to enact an x-ray detectable change of shape of the implant. Gerow cannot detect an impending rupture or fold, a failure that is solved by the present invention, as highlighted in claims 20-23. Applicant's rupture indicator, within a separate external envelope from the internal envelope containing the implant filling material, serves as a warning to the patient, that the prosthesis has been compromised or ruptured and medical care is urgently needed before there is any leakage or escape of silicone gel into the surrounding body tissues.

The present invention has numerous novel and non-obvious advantages over the references cited by the Examiner. It is respectfully submitted that all of the claims are in order for allowance and early notice to that effect is respectfully requested.

Respectfully submitted,

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